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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I General Information

Date Prepared: January 30, 2014

Establishment

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Mail Code D02
Malvern, PA 19355, USA
Registration Number: 2240869

Manufacturer

Siemens AG
Henkestrasse 127
D-91052 Erlangen, Germany
Registration Number: 3002808157

SIEMENS SHENZHEN MAGNETIC RESONANCE LTD.
Siemens MRI Center
Hi-Tech Industrial park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057, P.R. CHINA
Registration Number: 3004754211

Contact Person

Cordell L. Fields, Esq.
Regulatory Affairs Technical Specialist
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Malvern, PA 19355, USA
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Classification and Device Name

Trade name:	MAGNETOM Artis Combi Suite for the MAGNETOM systems Aera and Skyra.
Classification Name:	Regulation Description: - Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Regulation number:	21 CFR § 892.1000
Device Class:	II
Product Code:	Primary: LNH; Secondary: MOS

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II Safety and Effectiveness Information Supporting Substantial Equivalence

Device Description
MAGNETOM Artis Combi Suite is the marketing name for the modification of MAGNETOM Aera and MAGNETOM Skyra to include a modified dockable table for use with a standalone Artis system in a clinical workflow. The market name, MAGNETOM Artis Combi Suite, refers to a sales bundle of single items that have been combined to build up a patient transfer workflow from one medical device to another.

MAGNETOM Artis Combi Suite enables the user to move a patient via a patient transfer board from the patient table of a angiography system of the Siemens Artis family to the MR scanner.

The intended use of the MAGNETOM Aera and MAGNETOM Skyra as well as Artis imaging systems remains unchanged.

The MAGNETOM Artis Combi Suite will only be available for MAGNETOM systems Aera and Skyra and will be available as an option to new manufactured scanners; existing scanners can be upgraded to this sales bundle. The sales bundles include new hardware for the MAGNETOM systems Aera and Skyra.

Substantial Equivalence
Sales bundle MAGNETOM Artis Combi Suite for the MAGNETOM systems Aera and Skyra is substantially equivalent to the following current legally marketed devices (please refer to **Table 1**):

Table 1: Predicate device(s) for MAGNETOM Artis Combi Suite for the MAGNETOM systems Aera and Skyra

Predicate Device Name	FDA Clearance Number / Date	Manufacturer	Manufacturer, Product Code	Claim Substantial Equivalence to
syngo MR D 13A for MAGNETOM Aera, Skyra, Verio and Avanto	K121434, cleared November 5, 2012	Siemens AG	LNH	- MAGNETOM Aera and Skyra with *syngo* MR D13A - Tim Dockable Table
MAGNETOM Skyra with TimTX TrueShape and *syngo* MR D13C	K123510, cleared May 17, 2013	Siemens AG	LNH	- MAGNETOM Skyra with *syngo* MR D13C - Tim Dockable Table

Safety and Effectiveness
The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions

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USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

The MAGNETOM systems Aera and Skyra with sales bundle MAGNETOM Artis Combi Suite conform to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

Indications for Use
Your MAGNETOM MR system [Aera / Skyra] is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Your MAGNETOM MR system [Aera / Skyra] may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

Conclusion as to Substantial Equivalence
MAGNETOM Aera and MAGNETOM Skyra and software *syngo* MR D13A with MAGNETOM Artis Combi Suite as well as MAGNETOM Skyra and software *syngo* MR D13C with MAGNETOM Artis Combi Suite has the same intended use and the same technical characteristics as the predicate devices with respect to the magnetic resonance features and functionalities. The differences between the subject device and the predicate devices, which include the aforementioned hardware, give the systems MAGNETOM Aera and MAGNETOM Skyra with SW *syngo* MR D13 and Artis family additional capabilities by allowing the user to move a patient via a patient transfer board from the patient table of a angiography system of the Siemens Artis family to the MR scanner. There are no new issues of safety or effectiveness introduced with the MAGNETOM Artis Combi Suite. The functionality of MAGNETOM Artis Combi Suite remains similar to that of the predicate devices, MAGNETOM Aera and MAGNETOM Skyra with software *syngo* MR D13A and *syngo* MR D13C for MAGNETOM Skyra.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Siemens Medical Solutions USA, Inc.
% Cordell L. Fields, Esq.
Regulatory Affairs Technical Specialist
51 Valley Stream Parkway, Mail Code D02
MALVERN PA 19355

Re: K140253
Trade/Device Name: MAGNETOM Artis Combi Suite for the MAGNETOM systems Aera and Skyra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: January 30, 2014
Received: January 31, 2014

Dear Mr. Fields:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

k140253

Device Name
"MAGNETOM Artis Combi Suite" for the MAGNETOM systems Aera and Skyra

Indications for Use *(Describe)*
The MAGNETOM MR system [Aera/Skyra] is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM MR system [Aera/Skyra] may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*